



Office for Human Research Protections  
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November 1, 2007

Vimal Chaitanya, Ph.D.  
Vice President for Research, Graduate Studies and International Programs  
New Mexico State University  
Office of the Vice President for Research, Graduate Studies and International Programs  
MSC 3RES  
PO Box 30001  
Las Cruces, NM 88003-8001

**RE: Human Research Subject Protections Under Federalwide Assurance 451**

**Research Project:** The Impact of Education in Navajo Nation Border Community Public Schools on the Hearts, Minds, and Spirits of Navajo Students (Code named The Navajo Racism Project by the Navajo Institute for Social Justice)

**Principal Investigator:** Scott Wendell Bray, Ph.D.

**Project Number:** NMSU Project Number 6012

Dear Dr. Chaitanya:

The Office for Human Research Protections (OHRP) has reviewed the New Mexico State University (NMSU) October 16, 2007 report that was submitted in response to an OHRP August 27, 2007, letter regarding the above-referenced research.

In its August 27, 2007 letter, OHRP made the following findings:

- (1) OHRP found that the NMSU document entitled Principles and Procedures for the Conduct of Research Involving Human Subjects (hereinafter NMSU document) (dated July 1, 2007) failed to include adequate written procedures for ensuring prompt reporting to the institutional review board (IRB), appropriate institutional officials, the head of the sponsoring federal department or agency, if any, and OHRP of (i) ... any serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of the IRB; and (ii)

any suspension or termination of IRB approval, as required by HHS regulations at 45 CFR 46.103(a) and 45 CFR 46.103(b)(5).

**Corrective Action:** OHRP notes that NMSU has revised the NMSU document (dated October 2007) to include the reporting of the above-referenced incidents.

- (2) OHRP found that the NMSU document did not include written procedures that the IRB would follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review as required by HHS regulations at 45 CFR 46.103(b)(4)(ii).

**Corrective Action:** OHRP notes that NMSU has revised the NMSU document (dated October 2007) to include written procedures for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

- (3) OHRP found that the NMSU IRB approved an informed consent document for the above-referenced study that failed to include or adequately address certain elements as required by HHS regulations at 45 CFR 46.116.

**Corrective Action:** OHRP acknowledges that NMSU IRB members are provided with the following reference documents, which will help ensure that the NMSU IRB only approves informed consent documents that contain the applicable informed consent elements as outlined in HHS regulations at 45 CFR 46.116: a copy of 45 CFR part 46, the OHRP IRB Guidebook, the OHRP Human Subject Regulations Decision Charts and an Informed Consent Checklist.

- (4) OHRP found that when reviewing the above-referenced study the NMSU IRB lacked sufficient information to make the determinations required for approval of research under HHS regulations at 45 CFR 46.111.

**Corrective Action:** OHRP acknowledges that NMSU IRB members will be provided with the following reference documents, which will assist them in determining that all applicable 45 CFR 46.111 criteria are satisfied prior to approving research: a copy of the 45 CFR part 46, the OHRP IRB Guidebook, the OHRP Human Subject Regulations Decision Charts and a Checklist for IRB Review..

OHRP finds that the corrective actions noted above adequately address OHRP's determinations and are appropriate under the NMSU FWA. As a result, there should be no need of further involvement of OHRP in this matter.

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OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Lisa A. Rooney, J.D.  
Compliance Oversight Coordinator

Cc: Ms. Manuela L. Zuezada-Aragon, Director, Compliance and Research Administration,  
New Mexico State University (NMSU)  
Dr. John Irvine, IRB Chair, NMSU  
Dr. Scott Wendell Bray  
Dr. Ivor Pritchard, OHRP  
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